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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/593,828	06/13/2000	Steven Rosen	6510-138US1	7507

7590

06/23/2003

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EXAMINER

MONSHIPOURI, MARYAM

ART UNIT

PAPER NUMBER

1652

DATE MAILED: 06/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Handwritten notes:
GST 4 mouse
1, 2, 3, 4, 10, 11
mouse GST 9
CDNA human GST 4 d
protein 8
Full length GST 4 d
c-DNA GST 4 d
human GST d + GST B
genomic.

Office Action Summary

Application No.
09/593,828

Applicant(s)
Rosen et al.

Examiner
Maryam Monshipouri

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on RCE request filed 4/15/2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-70 is/are pending in the application.
- 4a) Of the above, claim(s) 1-4 and 13-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-12 and 58-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(e) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement (e) (PTO-1449) Paper No(s) 1, 22, 2 6) ☐ Other:

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A **Request for Continued Examination** under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. **Applicant's submission filed on 4/15/2003 (paper # 23) has been entered.**

Claims 5-12 and newly presented claims 58-70 are still at issue and are present for examination. Claims 1-4 and 13-57 are withdrawn as drawn to non-elected invention.

Applicants' arguments filed on 4/15/2003, paper No. 24, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

DETAILED ACTION

Claims 5-12, and 58-70 directed to **elected species, namely human GST α** , are under examination on the merits.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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2. Claims 5-7, 9-12, 58-67 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner could not find support for the phrase "GST-4 polypeptide, wherein said GST-4 polypeptide comprises an amino acid sequence that is at least 85% identical to SEQ ID NO:8" recited in claim 5 (and its dependent claims 6-7, 9-12, 58-70) in the specification. Upon a complete review and examination of the disclosure it is clear that the term GST-4 polypeptides is used by the applicant to refer generically to at least human and murine GST4 polypeptides (see for example page 9 of the disclosure) . However, murine GST polypeptides display sequence identities (based on examiner's own search of sequences in commercial databases) in orders of less than 80% identity to SEQ ID NO:8 of this invention. Since the examiner could not find "the 85% identity to SEQ ID NO:8" limitation, assigned to GST-4 polypeptides, and said phrase is concluded to be **new matter**. Applicant is advised to either delete said phrase from the claim or kindly refer the examiner to the appropriate page wherein such limitation of GST4 polypeptides is recited.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 69-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as

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the invention. The term "functional domain" in claim 69 and its dependent claim 70 is indefinite. Applicant has not defined this term in the specification. Hence, it is unclear as to what is the structural and functional requirements of said domain.

5. *Claim Rejections - 35 USC § 102*

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 5-7, 8-12 and 58-70 are rejected under 35 U.S.C. 102(a) as being anticipated by Lee et al. (cited previously) . It is noted that applicant claims benefit to a provisional application filed 7/20/1999. However, SEQ ID NO:10 has not been disclosed in said provisional application and said sequence can only benefit from the filing date of instant application which is 6/13/2000. In view of this priority date (i.e. 6/13/2000) Lee discloses a DNA sequence having 100 % identity to SEQ ID NO:10, (anticipating claims 6, 8, 9, 63-67) that inherently encodes SEQ ID NO:8 (anticipating claim 5) having a "functional domain" (anticipating claims 69-70) and can

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inherently encode a product that can catalyzes the transfer of a sulfate group from a donor to a selecting ligand, anticipating claims 7, 58-62, as well as expression cassettes (see materials and Methods of Lee) and cells comprising SEQ ID NO:10, anticipating claims 9-11 and methods of expressing (see page 547) said sequence (anticipating claim 12). Preparation of said expression cassettes requires that said DNA sequences be dissolved in some buffer prior to being inserted into said expression cassette. Said buffer can be considered to be a composition comprising SEQ ID NO:10, anticipating claim 68.

6. Claims 6-7, 8, 9-12, 61-62, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Bistrup (cited previously). As mentioned previously, Bistrup teaches and claims an isolated DNA sequence that has glycosyl sulfotransferase function (ie GST-3, which catalyzes the transfer of a sulfate group from a donor to an L-selecting ligand, namely GlyCAM-1, see column 26). Since the exact difference between the function of human GST4 α of this invention and GST-3 of Bistrup is not clear, it is believed that Bistrup's patent meets all the limitations of claims 7, 58, 61-62 of this invention. Further, the DNA sequence of Bistrup shows 34.1% identity to SEQ ID NO:4 of this invention. Due to the fact that upon changing the sequence alignment parameters Bistrup's sequence can be easily demonstrated to have at least 35% identity to SEQ ID NO:4 of this invention it is believed that Bistrup also claims a sequence that is "substantially identical" (see the definition provided in page 9 of the specification) to SEQ ID NO:4 of this invention, anticipating claim 6. Bistrup's sequence also is able to hybridize to SEQ

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ID NO:4 of this invention under stringent conditions recited in claim 8 anticipating said claim. Similarly the expression cassettes and host cells of Bistrup (see patented claims 2-4) anticipate claims 9-11 of this invention, respectively. Bistrup also teaches methods of expressing its DNA (see Bistrup's claim 5) and various buffers and vector compositions comprising its DNA, anticipating claims 12 and 68.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Maryam Monshipouri, Ph.D. whose telephone number is (703) 308-1083.

The Examiner can normally be reached daily from 8:30 A.M. to 5:00 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. P. Achutamurthy, can be reached at (703) 308-3804. The OFFICIAL fax number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.


MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER